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भारतीय मानक

चिकित्सीय विद्युत उपस्कर

भाग 2 सुरक्षा के लिए विशिष्ट अपेक्षाएँ

अनुभाग 29 रेडियोथेरेपी सिमुलेटर

Indian Standard

MEDICAL ELECTRICAL EQUIPMENT

PART 2 PARTICULAR REQUIREMENTS FOR THE SAFETY

Section 29 Radiotherapy Simulators

ICS 11.040.60

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BUREAU OF INDIAN STANDARDS
MANAK BHAVAN, 9 BAHADUR SHAH ZAFAR MARG
NEW DELHI 110002

May 2008 **Price Group 10**

Electromedical Equipment Sectional Committee, MHR 15

NATIONAL FOREWORD

This Indian Standard (Part 2/Sec 29) which is identical with IEC 60601-2-29 : 1999 'Medical electrical equipment — Part 2-29 : Particular requirements for the safety of radiotherapy simulators' issued by the International Electrotechnical Commission (IEC) was adopted by the Bureau of Indian Standards on the recommendation of the Electromedical Equipment Sectional Committee and approval of the Medical Equipment and Hospital Planning Division Council.

The use of radiotherapy simulators may expose patients to danger if the equipment design does not satisfy standards of electrical, mechanical and ionizing radiation safety. The equipment may also cause danger to persons in the vicinity if the equipment itself fails to contain the ionizing radiation adequately and/or if there are inadequacies in the design of the simulator room.

This particular standard establishes requirements to be complied with by manufacturers in the design and construction of radiotherapy simulators; it does not attempt to define their optimum performance requirements. Its purpose is to identify those features of design that are regarded, at the present time, as essential for the safe operation of such equipment; it places limits on the degradation of equipment performance beyond which it can be presumed that a fault condition exists, for example, a component failure, and where an interlock then operates to prevent continued operation of the equipment.

This standard is to be read in conjunction with IS 13450 (Part 1) : 2008 'Medical electrical equipment: Part 1 General requirements for safety (*first revision*)'. In this standard reference appears to IEC 60601-1 : 1988 for which we had identical standard IS 13450 (Part 1) : 1994. This has, however, been revised as IS 13450 (Part 1) : 2008 and as such the clause numbers have been slightly modified. Therefore, in view of taking the latest standard into consideration special care is to be taken while cross referring.

The text of IEC Standard has been approved as suitable for publication as an Indian Standard without deviations. Certain conventions are, however, not identical to those used in Indian Standards. Attention is particularly drawn to the following:

a) Wherever the words 'International Standard' appear referring to this standard, they should be read as 'Indian Standard'.

b) Comma (,) has been used as a decimal marker while in Indian Standards, the current practice is to use a point (.) as the decimal marker.

In this adopted standard, reference appears to certain International Standards for which Indian Standards also exist. The corresponding Indian Standards which are to be substituted in their respective places are listed below along with their degree of equivalence for the editions indicated:

International Standard	*Corresponding Indian Standard*	*Degree of Equivalence*
IEC 60601-1:1988 Medical electrical equipment — Part 1 : General requirements for safety	IS 13450 (Part 1) : 2008 Medical electrical equipment: Part 1 General requirements for safety (*first revision*)	Technically Equivalent
IEC 60601-2-7 : 1998 Medical electrical equipment — Part 2-7: Particular requirements for the safety of high-voltage generators of diagnostic X-ray generators	IS 13450 (Part 2/Sec 7) : 2006 Medical electrical equipment: Part 2 Particular requirements for the safety, Section 7 High-voltage generators of diagnostic X - ray generators	Identical
IEC/TR 60788 : 1984 Medical radiology — Terminology	IS 13807 : 1994 Medical radiology — Terminology	do

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Indian Standard

MEDICAL ELECTRICAL EQUIPMENT

PART 2 PARTICULAR REQUIREMENTS FOR THE SAFETY

Section 29 Radiotherapy Simulators

SECTION ONE – GENERAL

The clauses and subclauses of this section of the General Standard apply, except as follows:

1 Scope and object

1.1 Scope

Addition:

This Particular Standard applies to RADIOTHERAPY SIMULATORS:

- that use diagnostic X-RAY EQUIPMENT to simulate physically a RADIOTHERAPY RADIATION BEAM, so that the TREATMENT VOLUME to be subjected to IRRADIATION during RADIOTHERAPY can be localized, and the position and size of the RADIOTHERAPY RADIATION FIELD can be confirmed;
- intended exclusively for RADIOTHERAPY simulation as a prelude to intended RADIOTHERAPY, and not for any other purpose such as general diagnostic examinations;
- used within the environmental and electrical supply conditions SPECIFIED in the technical description;
- comprising the following parts:
  - a system for producing an X-RAY BEAM, which simulates the geometry of the RADIOTHERAPY RADIATION BEAM;
  - a system for producing images of the transmitted X-RAY BEAM, for example, either by RADIOGRAPHY or RADIOSCOPY;
  - an assembly to control the size and position of the RADIATION BEAM and to delineate the intended treatment area;
  - a mechanical structure that physically simulates the geometry and movements of the RADIOTHERAPY EQUIPMENT and supports the imaging system;
  - a PATIENT SUPPORT system.

1.2 Object

Addition:

This Particular Standard establishes requirements to ensure the IONIZING RADIATION safety and enhanced mechanical and electrical safety of RADIOTHERAPY SIMULATORS; it identifies geometrical parameters that are critical for the accurate simulation of a RADIOTHERAPY treatment.

1.3 Particular Standards

Additional subclauses:

1.3.101 Relationship to the General Standard.

NOTE – See appendix L for normative references

The requirements of this Particular Standard take priority over those of all other standards; it is to be read in conjunction with IEC 60601-1 (1988), *Medical electrical equipment – Part 1: General requirements for safety*, its amendments 1 (1991) and 2 (1995), and corrigendum (1995) – hereinafter referred to as the General Standard – which it amends and supplements.

Where there is no corresponding section, clause or subclause in this Particular Standard, the section, clause or subclause of the General Standard, although possibly not relevant, applies without modification. Where it is intended that any part of the General Standard, although possibly relevant, is not to be applied, a statement to that effect is given in this Particular Standard. Unless otherwise stated, all clauses of the General Standard apply.

As in the General Standard, the requirements are followed by compliance tests. The term "this standard" is used throughout to refer to the General Standard and this Particular Standard taken together.

The numbering of sections, clauses and subclauses of this Particular Standard corresponds to that of the General Standard (but see 29.1 b)). The changes to the text of the General Standard, or its Collateral Standards, are SPECIFIED by the use of the following words:

"Replacement" means that the clause or subclause of the General/Collateral Standard is replaced completely by the text of this Particular Standard.

"Addition" means that the text of this Particular Standard is additional to the requirements of the General/Collateral Standard.

"Amendment" means that the clause or subclause of the General/Collateral Standard is amended as indicated by the text of this Particular Standard.

Subclauses, figures or tables that are additional to those of the General Standard are numbered starting from 101; additional annexes are lettered AA, BB, etc., and additional items aa), bb), etc.

1.3.102 Relationship to other standards and documents

a) IEC 60601-2-7

This standard applies to HIGH-VOLTAGE GENERATORS of diagnostic X-RAY GENERATORS used with RADIOTHERAPY SIMULATORS (see 29.1 a)).

b) IEC 61217

This standard gives guidance on the designation of EQUIPMENT movements, the marking of scales, their zero positions, and the direction of movement with increasing value (see 6.3.101 a)).

1.5 Collateral Standards

Additional subclauses:

1.5.101 IEC 60601-1-1

This Collateral Standard does not apply.

1.5.102 IEC 60601-1-2

All clauses and subclauses of this Collateral Standard, together with the additions given in clause 36, apply to RADIOTHERAPY SIMULATORS and their integral INFORMATION TECHNOLOGY EQUIPMENT (ITE).

NOTE – IEC 60601-1-2 applies to EQUIPMENT and ITE used in medical applications. RADIOTHERAPY SIMULATORS and their integral ITE are not excluded from compliance with IEC 60601-1-2; at the date of publication of this standard it has not been possible to determine whether further amendments to its requirements or tests will be necessary.

1.5.103 IEC 60601-1-3

All clauses and subclauses of this Collateral Standard apply, except as amended in clause 29.

1.5.104 IEC 60601-1-4

All clauses and subclauses of this Collateral Standard apply (see 52.1 b)).

2 Terminology and definitions

Addition:

NOTE – Annex AA lists all defined terms alphabetically with their source reference.

Definitions of additional terms used in this Particular Standard.

2.1.101

DELINEATED RADIATION BEAM
that part of the RADIATION BEAM bordered by the shadow cast by the DELINEATORS

2.1.102

DELINEATED RADIATION FIELD
area of the DELINEATED RADIATION BEAM intercepted on a plane perpendicular to the REFERENCE AXIS

2.1.103

DELINEATOR(s)
means for defining the border(s) of the simulated RADIATION FIELD

2.1.104

RADIOTHERAPY SIMULATOR (hereinafter referred to as SIMULATOR)
EQUIPMENT that uses X-RAY EQUIPMENT to simulate geometrically parameters of movements and RADIATION FIELDS of RADIOTHERAPY EQUIPMENT so as to assist with the planning of PATIENT treatments

5 Classification

Replacement:

EQUIPMENT and its APPLIED PARTS shall be classified by marking and/or identification as described in clause 6. This includes:

5.1 According to the type of protection against electric shock:

– CLASS I EQUIPMENT.

5.2 According to the degree of protection against electric shock:

– TYPE B APPLIED PARTS.

5.3 According to the degree of protection against ingress of water detailed in the current edition of IEC 60529 (see 6.1 l)):

– IPX0, unless otherwise SPECIFIED.

5.4 According to the method(s) of sterilization or disinfection recommended in the INSTRUCTIONS FOR USE.

5.5 According to the degree of safety of application in the presence of a FLAMMABLE ANAESTHETIC MIXTURE WITH AIR, or WITH OXYGEN OR NITROUS OXIDE:

– EQUIPMENT not suitable for use in the presence of a FLAMMABLE ANAESTHETIC MIXTURE WITH AIR or WITH OXYGEN OR NITROUS OXIDE.

5.6 According to the mode of operation:

– Suitable for continuous connection to the SUPPLY MAINS in the STAND-BY STATE and for SPECIFIED LOADINGS, unless otherwise SPECIFIED.

6 Identification, marking and documents

6.3 Marking of controls and instruments

Additional subclause:

6.3.101 Provision of scales and indications for moving parts

a) The following shall be provided:

- a numerical indication of the dimensions of the DELINEATED RADIATION FIELD at a SPECIFIED distance;
- an indication by light of the RADIATION BEAM and the DELINEATED RADIATION FIELD;
- an indication of the position of the ISOCENTRE;
- means for indicating the FOCAL SPOT TO SKIN DISTANCE;
- an indication of the position of the REFERENCE AXIS on entry to the PATIENT or X-RAY IMAGE RECEPTOR;
- an indication to the OPERATOR, associated with the angular position of the DELINEATED RADIATION BEAM, of the possible WEDGE FILTER direction(s) for the RADIOTHERAPY EQUIPMENT being simulated;
- a numerical indication of the distance from the FOCAL SPOT to the IMAGE RECEPTOR PLANE;
- a numerical indication of the distance from the ISOCENTRE to the FOCAL SPOT when this parameter is adjustable;
- scale readouts complying with the conventions of IEC 61217, for all available movements of GANTRY, RADIATION HEAD and BLDS, DELINEATORS, X-RAY IMAGE RECEPTOR and PATIENT SUPPORT (see 1.3.102 b)).

b) In order to reduce the possibility of error when transferring data between SIMULATORS and RADIOTHERAPY EQUIPMENT having other scale conventions, SIMULATORS may incorporate additional scale readouts supporting other scale conventions, in which case the scale convention then being DISPLAYED by the SIMULATOR shall be unambiguous.

Compliance is checked by inspection.

6.7 Indicator lights and push-buttons

a) Colours of indicator lights

Addition:

Where indicator lights are used on the TREATMENT CONTROL PANEL (TCP), or other CONTROL PANELS, the colours of the lights shall be in accordance with the following:

– RADIATION BEAM "on"	yellow [1];
– READY STATE	green [1];
– urgent action required in response to an unintended state of operation	red;
– PREPARATORY STATE	other colour.

Light emitting diodes (LEDs) are not considered to be indicator lights when:

- on any CONTROL PANEL, all indications for which no particular colour is required are given by LEDs of the same colour; and
- the indications, for which particular colours are required, are clearly distinguishable.

6.8 Accompanying documents

6.8.1 General

Addition:

NOTE – The term 'ACCOMPANYING DOCUMENTS' includes 'INSTRUCTIONS FOR USE' and 'technical description'. Clauses and subclauses in this Particular Standard that require the provision of information in any of these three documents are given in table 101.

6.8.2 Instructions for use

a) General information

Addition:

- INSTRUCTIONS FOR USE shall contain:
  - an explanation of the function of all INTERLOCKS and other RADIATION safety devices;
  - instructions for checking their correct operation;
  - a recommendation of the frequency with which such checks should be made;
  - the recommended inspection or replacement intervals for parts having a safety function that are subject to impairment caused, during NORMAL USE of the EQUIPMENT, by the effects of IONIZING RADIATION on the dielectric and/or mechanical strength of those parts;
  - a list of those parts of the EQUIPMENT that are likely to be influenced by the climatic conditions simulated by the humidity preconditioning treatment test 4.10, and a list of the parts that have been tested under this condition.

---

[1] In the SIMULATOR room, or in other locations, these states may need urgent action or caution; different colours, in accordance with table III of the General Standard, may therefore be used in such locations.

j) Environmental protection

Addition:

– Include data to assist the USER'S RADIOLOGICAL PROTECTION adviser regarding:

- the range of available DELINEATED RADIATION FIELD dimensions;
- the maximum available RADIATION FIELD dimensions and the distance from the FOCAL SPOT at which this is SPECIFIED;
- the available directions of the RADIATION BEAM;
- the location of the FOCAL SPOT referred to an accessible point on the X-RAY SOURCE ASSEMBLY/RADIATION HEAD;
- the maximum available X-RAY TUBE VOLTAGE.

6.8.3 Technical description

a) General

Addition:

The technical description shall provide full details of the environmental conditions and power supply required for NORMAL USE.

Addition:

Table 101 – Clauses and subclauses in this Particular Standard that require the provision of information in the ACCOMPANYING DOCUMENTS, the INSTRUCTIONS FOR USE, and the technical description

NOTE – The "check reference" is given as an aid for checking the availability of compliance documentation.

Check reference	ACCOMPANYING DOCUMENTS	INSTRUCTIONS FOR USE	Technical description
1		5.4	
2		6.8.2 a) and j)	
3			6.8.3 a)
4	16 aa)		
5			18 b)
6		22.4.1 a) 1) and a) 2)	
7			22.4.1 a) 4)
8		22.4.2 e)	
9		22.4.3 e)	
10	22.7.101		
11	28.101 b)		
12			29.203.3
13	29.208.2		
14	36		
15		52.1 b)	

SECTION TWO – ENVIRONMENTAL CONDITIONS

The clauses and subclauses of this section of the General Standard apply, except as follows.

10 Environmental conditions

Addition:

NOTE – See 1.1, third dash, and 6.8.3 a): *Addition.*

10.2.2 Power supply

a) EQUIPMENT shall be suitable for a power supply having:

Amendment of the second dash:

- a sufficiently low internal impedance to prevent voltage fluctuations, between the on-load and off-load steady states, exceeding ±5 %.

SECTION THREE – PROTECTION AGAINST ELECTRIC SHOCK HAZARDS

The clauses and subclauses of this section of the General Standard apply, except as follows:

16 ENCLOSURES and PROTECTIVE COVERS

Additional item:

aa) Where the requirements of this clause are wholly or partly met by the nature of the installation, compliance test methods shall be SPECIFIED in the ACCOMPANYING DOCUMENTS (see also 57.1 a)).

Compliance at installation should be checked by inspection and test.

18 Protective earthing, functional earthing and potential equalization

b) *Addition:*

The technical description shall contain advice that PROTECTIVE EARTH CONDUCTORS, permanently fixed at installation to connect PROTECTIVE EARTH TERMINALS of EQUIPMENT to an external protective system, should be adequately dimensioned according to the requirements of national regulations, for each installation and for the maximum fault current that may occur there.

Compliance at installation should be checked by inspection and test in accordance with the applicable national regulations (see 18 f) and also 6.5, 57 and 58).

f) *Replacement:*

Replace the first paragraph of the compliance test by the following:

A current of 25 A or 1,5 times the rated current applicable to that part of the EQUIPMENT *under test, whichever is the lesser (±10 %), from a current source with a frequency of 50 Hz or 60 Hz and a no load voltage not exceeding 6 V, is passed for between 5 s and 10 s through the* PROTECTIVE EARTH TERMINAL *and each* ACCESSIBLE METAL PART *which would become live in case of failure of* BASIC INSULATION.

19 Continuous LEAKAGE CURRENTS and PATIENT AUXILIARY CURRENTS

19.1 General requirements

b) *Replacement:*

The SPECIFIED values of the continuous EARTH LEAKAGE CURRENT and the ENCLOSURE LEAKAGE CURRENT apply at normal operating temperature with a supply representative of a permanently installed power supply in any combination of the following:

- in NORMAL CONDITION (NC) and in the SPECIFIED SINGLE FAULT CONDITION (SFC) (see 19.2);
  1) with the EQUIPMENT energized in the PREPARATORY STATE and with the worst possible combination of simultaneously powered movements, and
  2) operating at maximum power consumption.

The measured values for continuous EARTH LEAKAGE CURRENT and ENCLOSURE LEAKAGE CURRENT measured in NC, as required in 1) and 2) above, shall not exceed the allowable values given in 19.3.

19.3 Allowable values

Amendment:

Amend the allowable values in table IV for TYPE B APPLIED PART, NC, as follows:

EARTH LEAKAGE current for equipment according to note[3)]	20 mA
ENCLOSURE LEAKAGE CURRENT	0,5 mA

SECTION FOUR – PROTECTION AGAINST MECHANICAL HAZARDS

The clauses and subclauses of this section of the General Standard apply, except as follows

22 Moving parts

Replacement:

22.4 Powered movements (see figures 101, 102 and 103)

For the PATIENT SUPPORT system, the requirements shall apply when it is unloaded and when it is loaded with a uniformly distributed mass of 135 kg.

NOTE 1 – The phrase "to set-up automatically" or "automatic set-up" is used to denote the moving of EQUIPMENT parts automatically to the positions required for the start of a PATIENT treatment simulation

NOTE 2 – The term "pre-programmed movements" is used where movement of EQUIPMENT parts takes place according to a previously planned programme, without intervention by the OPERATOR, during PATIENT treatment simulation; this is referred to as "pre-programmed treatment simulation"

22.4.1 GANTRY, RADIATION HEAD, X-RAY IMAGE RECEPTOR and PATIENT SUPPORT system

a) General

NOTE – "Failure of powered movements" is to be interpreted as the failure only of the SUPPLY MAINS associated with the powered movements.

1) Where the possibility exists that failure of a powered movement during NORMAL USE might result in the PATIENT becoming trapped, means shall be provided to permit the release of the PATIENT; these means shall be described in the INSTRUCTIONS FOR USE.
2) Where the RADIATION HEAD, or any other part, is provided with a device designed to reduce, in NORMAL USE, the risk of collision with the PATIENT, the operation and limitations of each device shall be described in the INSTRUCTIONS FOR USE.
3) Interruption or failure of powered movements or of the SUPPLY MAINS for the EQUIPMENT, shall cause any parts in motion to be stopped within the limits given in parts b) 3) and c) 3) of this subclause.
4) For automatic set-up, speed shall be reduced at least 5° before any planned stop angle and at least 25 mm before any planned stop position; the speed reduction shall be such that overshoot does not exceed 2° for angular displacements and 5 mm for linear displacements. Details of the speed reduction processes shall be included in the technical description.

Compliance is checked as follows:

1), 2) by inspection of the INSTRUCTIONS FOR USE and the facilities provided;

3) by interruption of the SUPPLY MAINS a) to powered movements, b) to the EQUIPMENT, and measurement of stopping distances. In order to eliminate the effects of variable personal reaction times, measurement shall start at the instant the personally actuated switch contacts open or close. In determining a stopping distance, the measurement shall be repeated five times; on each occasion, the part in motion shall stop within the allowable distance;

4) by inspection of the technical description and measurement.

b) Angular movements

1) The minimum speed available for each movement shall not exceed 1° × s^{-1}.

2) No speed shall exceed 7° × s^{-1}.

3) When rotating at the speed nearest to, but not exceeding, 1° × s^{-1}, the angle between the position of the moving part at the instant of operating any control to stop the movement and its final position, shall not exceed 0,5°, and it shall not exceed 3° for speeds in excess of 1° × s^{-1}.

Exceptions: Requirement 2) above shall not apply to the BEAM LIMITING SYSTEM (BLS) neither to the GANTRY rotation under the conditions SPECIFIED in 22.4.2 c) and 22.4.3 c).

c) Linear movements

1) The minimum speed available for the BEAM LIMITING DEVICES (BLDS), for displacements 20, 21, 22 and 23 of the DELINEATED RADIATION FIELD edges, 16, 17 and 18 of the X-RAY IMAGE RECEPTOR, and 9, 10 and 11 of the PATIENT SUPPORT system, shall not exceed 10 mm × s^{-1}.

2) No speed shall exceed 100 mm × s^{-1}.

3) When moving at speeds not exceeding 25 mm × s^{-1}, the distance between the position of the moving part at the instant of operating any control to stop the movement and its final position shall not exceed 3 mm, and it shall not exceed 10 mm for speeds in excess of 25 mm × s^{-1}.

Compliance of b) and c) is checked, using suitable measuring instruments, by measurement of speeds of moving parts and their stopping distances. In order to eliminate the effects of variable personal reaction times, measurement shall start at the instant the personally actuated switch contacts open or close. In determining a stopping distance, the measurement shall be repeated five times; on each occasion, the part in motion shall stop within the allowable distance (see also 22.4.2, 22.4.3, 22.7.101 and 27.101).

22.4.2 Operation of movements of EQUIPMENT parts from inside the SIMULATOR room

a) It shall not be possible to adjust motorized movements of EQUIPMENT parts which may cause physical injury to the PATIENT, without continuous simultaneous personal action by the OPERATOR on two switches.

NOTE – Linear or angular adjustments of BLDS or DELINEATORS, are not considered to be likely causes of injury to the PATIENT unless ACCESSORIES are fitted that do not have integral safety devices/touchguards or are otherwise considered to present a SAFETY HAZARD.

b) For EQUIPMENT intended to be set-up automatically, it shall not be possible to initiate or maintain movements associated with this condition without continuous simultaneous personal action by the OPERATOR on the automatic set-up switch and a switch common to all movements.

c) GANTRY angular speed may be increased to a maximum of 12° × s^{-1}, for positioning under manual control and, for EQUIPMENT that includes a COMPUTED TOMOGRAPHY (CT) capability, during the checking of a pre-programmed CT scan, provided that in both cases there is personal action by the OPERATOR on a "fast speed" enabling switch, followed by continuous personal action by the OPERATOR on the GANTRY rotation switch and a switch common to all movements.

d) The switches required above for a), b), and, when provided, for c), shall be located close to the PATIENT SUPPORT system, so that by careful observation the OPERATOR can avoid possible injury to the PATIENT. All switches, when released, shall be capable of stopping movement; one switch may be common to all movements. In each case, at least one of the required switches shall be HARD-WIRED.

e) The INSTRUCTIONS FOR USE shall contain advice that when a remotely controlled movement from the TCP, a pre-programmed treatment simulation or a CT scan is intended, a check should be made of all intended or planned movements with the PATIENT finally positioned, before the OPERATOR leaves the SIMULATOR room.

Compliance is checked by inspection.

22.4.3 Operation of movements of EQUIPMENT parts from outside the SIMULATOR room

a) It shall not be possible to adjust a movement parameter without continuous simultaneous personal action by the OPERATOR on that movement control switch and a switch common to all movements.

b) It shall not be possible to initiate or maintain movements associated with automatic set-up, without continuous simultaneous personal action by the OPERATOR on the automatic set-up switch and a switch common to all movements.

c) For EQUIPMENT that includes a pre-programmed CT facility, GANTRY angular speed may be increased to a maximum of $12° \times s^{-1}$, during pre-programmed CT scans, provided that there is continuous simultaneous personal action by the OPERATOR on the CT enabling switch and on a switch common to all movements.

d) When released, all switches required above for a), b), and, when provided, for c), shall be capable of stopping movement; one switch may be common to all movements. In each case, at least one of the required switches shall be HARD-WIRED.

e) The INSTRUCTIONS FOR USE shall include the recommendation that the OPERATOR shall have an unobstructed view of the PATIENT before and during the treatment simulation.

Compliance is checked by inspection.

22.7

Additional subclause:

22.7.101 Motors emergency stop

Readily identifiable and accessible means shall be provided in HARD-WIRED circuits near to, or on, the PATIENT SUPPORT system and the TCP, for emergency switching of all SUPPLY MAINS to the movement systems; when operated, any movement shall stop within the limits given in 22.4.1.

The means provided near to, or on, the TCP shall also TERMINATE IRRADIATION. The time to effect these disconnections shall not exceed 100 ms.

When any of the means are to be incorporated on site by the USER, the requirements and test procedures shall be SPECIFIED in the ACCOMPANYING DOCUMENTS.

Compliance is checked by inspection of the ACCOMPANYING DOCUMENTS, and by inspection and measurement of stopping distances and disconnection time using suitable measuring instruments; in order to eliminate the effects of variable personal reaction times, measurements shall start at the instant the personally actuated switch contacts open or close.

27 Pneumatic and hydraulic power

Additional subclause:

27.101 Change of pressure

If a SAFETY HAZARD can arise from a change in the pressure of a system used to provide power for movements, all movement shall stop from any speed within the limits SPECIFIED in 22.4.1.

Compliance is checked by simulation of a fault condition, the operation of protective devices and measurement of stopping distances.

28 Suspended masses

Additional subclause:

28.101 Attachment of ACCESSORIES

a) Where means are provided to permit the attachment of ACCESSORIES supplied by the MANUFACTURER, in particular those for the shaping of the RADIATION BEAM, such means shall be designed to retain those ACCESSORIES securely under all conditions of NORMAL USE.

Compliance is checked by inspection, and by consideration of design data and applied safety factors.

b) The ACCOMPANYING DOCUMENTS shall contain maintenance requirements and define the conditions and limits of use for the ACCESSORIES supplied; they should include guidance regarding design limits for ACCESSORIES manufactured or commissioned by the USER.

Compliance is checked by inspection.

SECTION FIVE — PROTECTION AGAINST HAZARDS FROM UNWANTED OR EXCESSIVE RADIATION

The clauses and subclauses of this section of the General Standard apply, except as follows:

29 X-RADIATION

Replacement:

29 X-RADIATION generated by SIMULATORS

29.1 General requirements

a) HIGH-VOLTAGE GENERATORS of diagnostic X-RAY GENERATORS used with SIMULATORS shall comply with the applicable requirements and tests of IEC 60601-2-7 (see 1.3.102 a)).

Compliance is checked by inspection of the X-RAY GENERATOR type test file.

b) SIMULATORS shall comply with the applicable requirements and tests of IEC 60601-1-3 (see 1.5.103) except as follows:

NOTE – Clause numbering (29.20n.n etc.) is identical with that used in IEC 60601-1-3

1) The following subclauses do not apply:

29.202.3 Confinement of EXTRA-FOCAL RADIATION

29.202.7 Indication by LIGHT FIELD-INDICATOR (see 6.3.101 a))

2) Replace the following subclause:

29.203.3 Interception of the X-RAY BEAM in RADIOSCOPY

Replacement:

IRRADIATION in RADIOSCOPY shall be prevented unless the BLDs are positioned such that the intended X-RAY FIELD is within the IMAGE RECEPTION AREA at the currently selected FOCAL SPOT TO IMAGE RECEPTOR DISTANCE.

Where means are available to reposition the IMAGE RECEPTION AREA such that,

- within the limits of its positioning, some part of the X-RAY FIELD lies outside the IMAGE RECEPTION AREA, and
- where a readjustment of the BLDs reduces the X-RAY FIELD so that it is fully within the IMAGE RECEPTION AREA,

RADIOSCOPY shall be possible only with the reduced X-RAY FIELD.

IRRADIATION shall again be prevented when any subsequent change extends this X-RAY FIELD beyond the IMAGE RECEPTION AREA. The technical description shall contain details of any operational limitations, routine tests, adjustments and advice applying to these features.

Compliance is checked by inspection and functional test, and by examination of the technical description.

3) The following subclauses do not apply:

29.203.4 Correspondence between X-RAY FIELD and IMAGE RECEPTION AREA

29.205 FOCAL SPOT TO SKIN DISTANCE

29.205.1 X-RAY EQUIPMENT for RADIOSCOPY

29.205.2 X-RAY EQUIPMENT for RADIOGRAPHY

29.205.3 Information in the ACCOMPANYING DOCUMENTS

4) Amend the following subclause:

29.206 ATTENUATION of the X-RAY BEAM

Amendment:

Add the following line to table 206:

PATIENT SUPPORT, RADIOTHERAPY SIMULATORS	5,0 mm

5) The following subclauses do not apply:

29.207 PRIMARY PROTECTIVE SHIELDING

29.207.1 Requirements

29.207.2 Test for ATTENUATION of RESIDUAL RADIATION

29.207.3 Test for ATTENUATION EQUIVALENT

29.208 Protection against STRAY RADIATION

29.208.1 Protection by distance

6) Replace the following subclause:

29.208.2 Control from a PROTECTED AREA

Replacement:

Means shall be provided to allow the following control functions only by OPERATOR action at the TREATMENT CONTROL PANEL situated within a PROTECTED AREA:

- selection and control of modes of operation;
- selection of LOADING FACTORS;
- actuation of the IRRADIATION SWITCH.

The IRRADIATION SWITCH shall be protected from accidental operation and require continuous pressure by the OPERATOR.

Means, compliant with the requirements of 22.4.1 and 22.4.3, shall be provided at the TREATMENT CONTROL PANEL for the remote control of powered movements for:

- GANTRY;
- RADIATION HEAD and BLDS;
- DELINEATED RADIATION FIELD;
- X-RAY IMAGE RECEPTOR;
- PATIENT SUPPORT.

The ACCOMPANYING DOCUMENTS shall contain:

- a warning against allowing persons, other than the PATIENT, to remain inside the SIMULATOR room during IRRADIATION;
- a statement drawing the attention of the USER to the need for providing the OPERATOR with means for verbal communication with, and an unobstructed view of, the PATIENT.

Compliance is checked by inspection of the EQUIPMENT and by examination of the ACCOMPANYING DOCUMENTS.

7) The following subclauses do not apply:

29.208.3 Designated SIGNIFICANT ZONES OF OCCUPANCY

29.208.4 SIGNIFICANT ZONES OF OCCUPANCY with limited STRAY RADIATION

29.208.5 Handgrips and control devices

29.208.6 Test for STRAY RADIATION

Additional subclause:

29.101 Adventitious IONIZING RADIATION

NOTE – Clause 29 of the General Standard has been replaced; its subclause 29.2 is reinstated here in a relevant form; it is not to be regarded as part of IEC 60601-1-3.

For EQUIPMENT or EQUIPMENT parts not intended to produce IONIZING RADIATION and which form part of a SIMULATOR, IONIZING RADIATION emitted by thermionic valves excited by voltages exceeding 5 kV shall not produce an ambient dose equivalent[2] $H^*(d)$, exceeding 5 µSv in one hour at a distance of 5 cm from any accessible surface.

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[2] See ICRU, Report 39: section 3.1.1 etc., or ICRU, Report 51: section 1.4.3/1.4.3.1.1, and ICRP 60: A.14, A.14.1, (A27) etc.

Compliance is checked by performing measurements of ambient dose equivalent, averaged over an area not exceeding 10 cm^2. Controls and adjustments are set at the position resulting in the maximum emission of X-RADIATION.

Single failures of components causing the least favourable situation are provoked in turn. In order to assess the dose due to small angle beams, use a RADIATION DETECTOR suitable for the emitted RADIATION ENERGY. Record the method, positions and results of measurements.

36 ELECTROMAGNETIC COMPATIBILITY

Replacement:

The requirements and tests of IEC 60601-1-2, with the additions to 36.201.1, 36.202 and 36.202.2 given below, shall apply to SIMULATORS and their integral ITE.

The site(s) used for measurements shall be typical of those generally used for the installation of SIMULATORS; they may be those of USERS or of the MANUFACTURER. Any allowances made shall be justified and included in the ACCOMPANYING DOCUMENTS.

36.201 EMISSIONS

36.201.1 Radio-frequency (RF) emissions

Addition:

aa) The requirements for compliance shall be those applying to CISPR 11, designated Group 1, Class A, PERMANENTLY INSTALLED EQUIPMENT.

bb) For radio-frequency EMISSIONS, the attenuation of ELECTROMAGNETIC DISTURBANCES by structures within the bounds of the exterior walls from which measurements are made at a distance, shall be regarded as though this was due to the inherent attenuation of the EQUIPMENT.

Compliance is checked by measurements, made in accordance with IEC 60601-1-2, at 30 m from the exterior walls of the building containing the location in which the EQUIPMENT has been installed.

36.202 IMMUNITY

Addition:

aa) The requirements for compliance shall be those applying to PERMANENTLY INSTALLED EQUIPMENT.

36.202.2 Radiated radio-frequency electromagnetic fields

Addition:

aa) For IMMUNITY to radio-frequency electromagnetic fields, the attenuation provided by the structural protection against IONIZING RADIATION shall be regarded as though this was due to the inherent attenuation of the EQUIPMENT.

Compliance is checked by tests made in accordance with IEC 60601-1-2. The test antenna shall be placed at a distance of 3 m from the outside of the structural protection against IONIZING RADIATION.

SECTION SIX – PROTECTION AGAINST HAZARDS OF IGNITION OF FLAMMABLE ANAESTHETIC MIXTURES

This section of the General Standard does not apply.

SECTION NINE – ABNORMAL OPERATION AND FAULT CONDITIONS; ENVIRONMENTAL TESTS

The clauses and subclauses of this section of the General Standard apply, except as follows:

52 Abnormal operation and fault conditions

52.1 *Replacement*:

52.1

a) EQUIPMENT shall be so designed and manufactured that, even in SFC, no SAFETY HAZARD exists (see 3.1 and clause 13).

NOTE – It is assumed that EQUIPMENT is operated according to the conditions of NORMAL USE, unless SPECIFIED otherwise in the following tests.

Compliance is fulfilled if:

The introduction of any of the SFCS described in 52.5, one at a time, does not lead directly to any of the SAFETY HAZARDS described in 52.4.

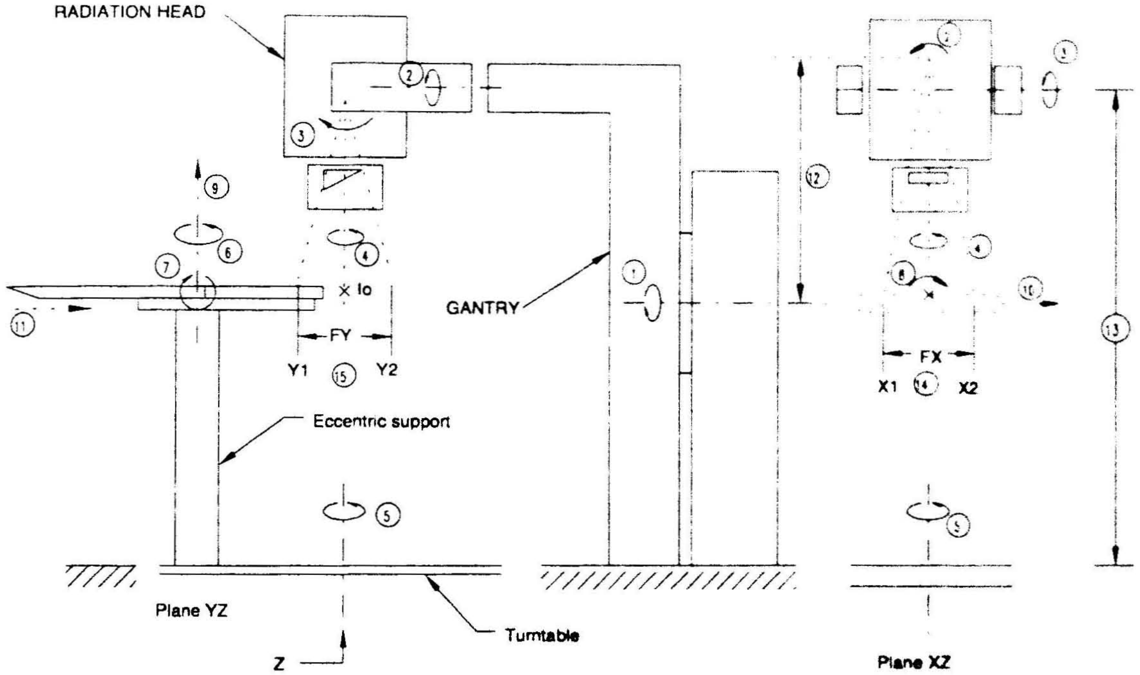
b) The safety of EQUIPMENT incorporating PROGRAMMABLE ELECTRONIC SUBSYSTEMS shall be assessed against the requirements of IEC Collateral Standard 60601-1-4 (see appendix L).

All relevant information regarding RESIDUAL RISK shall be included in the INSTRUCTIONS FOR USE.

Exception: IEC 60601-1-4 shall not be applied to projects/products when it can be shown that development has progressed beyond the stage where its detailed requirements cannot be applied; it has to be applied during project/product development and continued throughout the DEVELOPMENT LIFE-CYCLE.

Although it will not be possible to apply IEC 60601-1-4 fully in retrospect to existing products and to those that have progressed beyond the stage identified above, examination of available design and process control data may provide substantial verification; see also 52.211.1 of IEC 60601-1-4.

Compliance is checked by inspection of the INSTRUCTIONS FOR USE and the IEC 60601-1-4 RISK MANAGEMENT FILE.



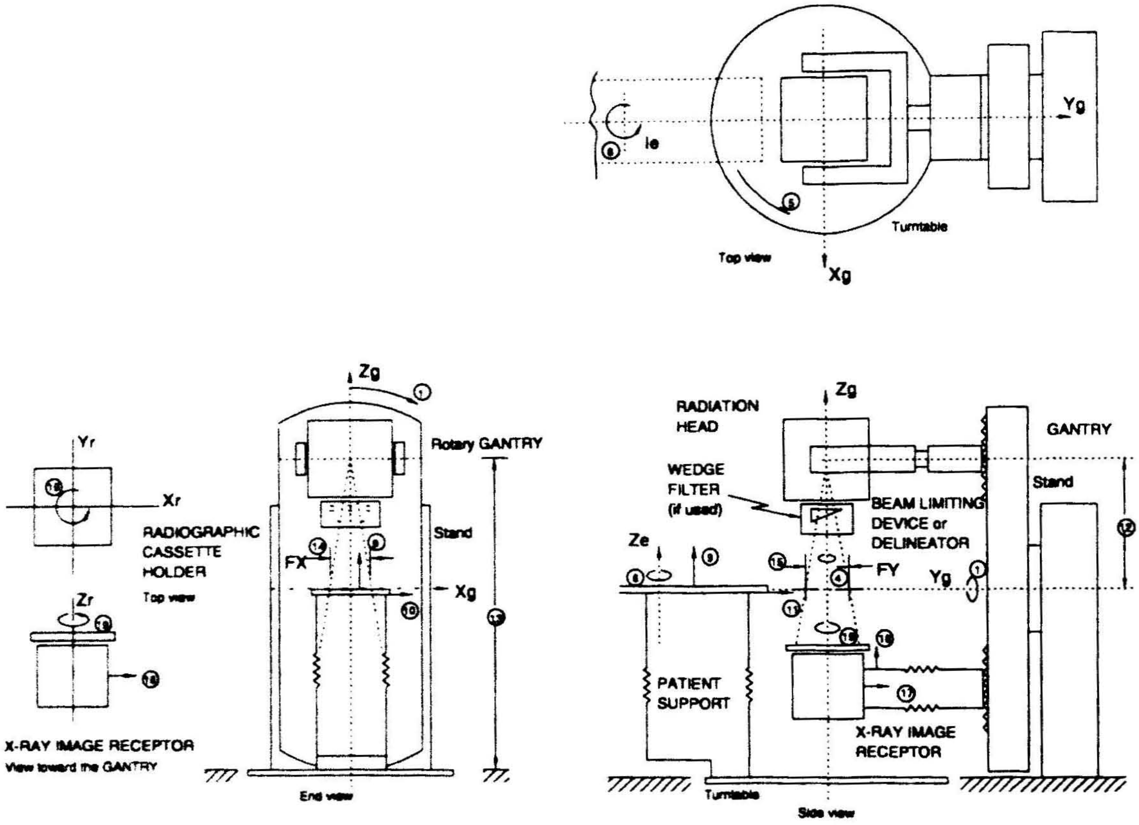
NOTE 1 – The axes, directions and dimensions corresponding to the numbers on these figures are listed in the accompanying table.

NOTE 2 – The elliptical arrows show clockwise rotations looking towards GANTRY for axes 1 and 8, away from GANTRY for axis 2, from right side of GANTRY for axes 3 and 7, up from ISOCENTRE, Io, for axis 4, up from ISOCENTRE for axis 5, up from table top for axis 6.

NOTE 3 – Symbols X1, X2, Y1 and Y2 designate the edges of RADIATION FIELD or DELINEATED RADIATION FIELD according to 6.4.1 of IEC 61217.

Figure 101 – EQUIPMENT movements and scales – Rotary GANTRY (adapted from IEC 60601-2-1) with identification of axes 1 to 8, directions 9 to 13, and dimensions 14 and 15
(see accompanying table)

This figure is identical to figure 13a in IEC 61217.



NOTE 1 – RADIOGRAPHIC CASSETTE HOLDER and/or X-RAY IMAGE RECEPTOR motions:

Direction 17: motion along Y-axis, parallel to axis 1;

Direction 18: motion along Z-axis, parallel to axis 4;

Axis 19: rotation.

NOTE 2 – Symbols Xr, Yr, Zr; Xg, Yg, Zg; and Ze are coordinates for X-RAY IMAGE RECEPTOR; GANTRY; and table top eccentric rotation coordinate systems respectively. Ie is the origin of the eccentric coordinate system.

Figure 102 – EQUIPMENT movements and scales – ISOCENTRIC RADIOTHERAPY SIMULATOR or TELERADIOTHERAPY EQUIPMENT, with identification of axes 1; 4 to 6; 19, of directions 9 to 12; 16 to 18 and of dimensions 14; 15 (see accompanying table)

This figure is identical to figure 13b in IEC 61217.

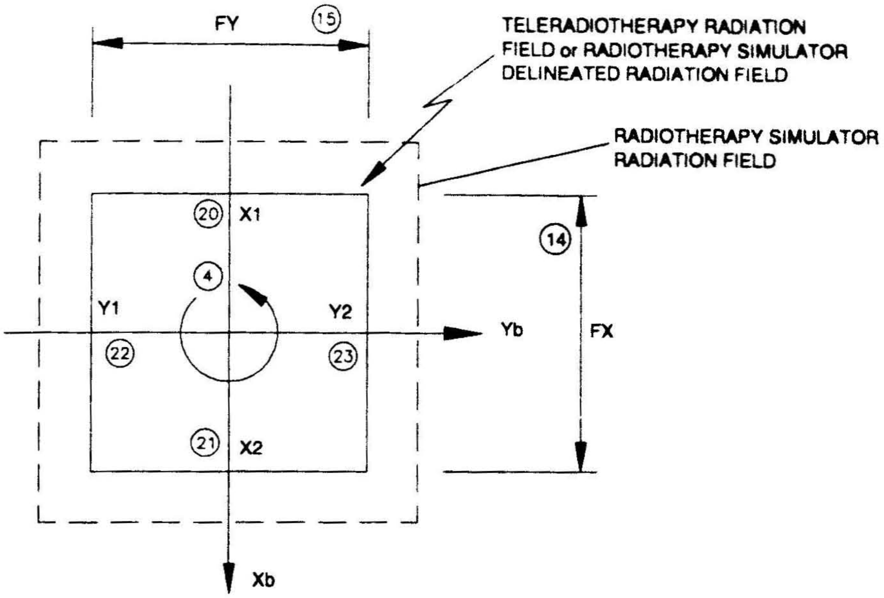

FY
⑮
TELERADIOTHERAPY RADIATION FIELD or RADIOTHERAPY SIMULATOR DELINEATED RADIATION FIELD
RADIOTHERAPY SIMULATOR RADIATION FIELD
⑳
X1
⑭
④
Y1
Y2
Yb
FX
㉒
㉓
㉑
X2
Xb

Figure 103 – EQUIPMENT movements and scales – View from RADIATION SOURCE of TELERADIOTHERAPY RADIATION FIELD or RADIOTHERAPY SIMULATOR DELINEATED RADIATION FIELD (see accompanying table)

This figure is identical to figure 13c in IEC 61217.

Axis 1	Rotation of GANTRY
Axis 2	Roll of the RADIATION HEAD
Axis 3	Pitch of the RADIATION HEAD
Axis 4	Rotation of the BEAM LIMITING DEVICE or DELINEATOR
Axis 5	ISOCENTRIC rotation of the PATIENT SUPPORT
Axis 6	Rotation of the table top about the eccentric support
Axis 7	Pitch of the table top
Axis 8	Roll of the table top
Direction 9	Vertical displacement of the table top
Direction 10	Lateral displacement of the table top
Direction 11	Longitudinal displacement of the table top
Direction 12	Displacement of RADIATION SOURCE from axis 1
Direction 13	Displacement of RADIATION SOURCE from floor at GANTRY angular position zero
Dimension 14	Dimension FX of the RADIATION FIELD or DELINEATED RADIATION FIELD in the Xb direction indicated in figure 101c at a specified distance from the RADIATION SOURCE (usually at the NORMAL TREATMENT DISTANCE)
Dimension 15	Dimension FY of the RADIATION FIELD or DELINEATED RADIATION FIELD in the Yb direction indicated in figure 101c at a specified distance from the RADIATION SOURCE (usually at the NORMAL TREATMENT DISTANCE)
Direction 16	X-RAY IMAGE RECEPTOR and/or RADIOGRAPHIC CASSETTE HOLDER motion along X axis perpendicular to axis 1 and axis 4
Direction 17	X-RAY IMAGE RECEPTOR and/or RADIOGRAPHIC CASSETTE HOLDER motion along Y axis parallel to axis 1
Direction 18	X-RAY IMAGE RECEPTOR and/or RADIOGRAPHIC CASSETTE HOLDER motion along Z axis parallel to axis 4
Axis 19	Rotation of the X-RAY IMAGE RECEPTOR and/or RADIOGRAPHIC CASSETTE HOLDER
Direction 20	Displacement from RADIATION BEAM AXIS to RADIATION FIELD or DELINEATED RADIATION FIELD edge X1 at a specified distance from the RADIATION SOURCE (usually the NORMAL TREATMENT DISTANCE)
Direction 21	Displacement from RADIATION BEAM AXIS to RADIATION FIELD or DELINEATED RADIATION FIELD edge X2 at a specified distance from the RADIATION SOURCE (usually at the NORMAL TREATMENT DISTANCE)
Direction 22	Displacement from RADIATION BEAM AXIS to RADIATION FIELD or DELINEATED RADIATION FIELD edge Y1 at a specified distance from the RADIATION SOURCE (usually at the NORMAL TREATMENT DISTANCE)
Direction 23	Displacement from RADIATION BEAM AXIS to RADIATION FIELD or DELINEATED RADIATION FIELD edge Y2 at a specified distance from the RADIATION SOURCE (usually at the NORMAL TREATMENT DISTANCE)

Appendix L
(normative)

References – Publications mentioned in this standard

This appendix of the General Standard applies, except as follows:

Addition:

The following normative documents contain provisions which, through reference in this text, constitute provisions of this International Standard. At the time of publication, the editions indicated were valid. All normative documents are subject to revision, and parties to agreements based on this International Standard are encouraged to investigate the possibility of applying the most recent editions of the normative documents indicated below. Members of IEC and ISO maintain registers of currently valid International Standards.

Addition:

IEC Standards:

IEC 60601-1:1988, *Medical electrical equipment – Part 1: General requirements for safety*
Amendment 1:1991
Amendment 2:1995

IEC 60601-2-7:1998, *Medical electrical equipment – Part 2: Particular requirements for the safety of high-voltage generators of diagnostic X-ray generators*

IEC 60788:1984, *Medical radiology – Terminology*

IEC 61217:1996, *Radiotherapy equipment – Co-ordinates, movements and scales*

Replacement:

Replace the reference to IEC 60601-1-4 by the following:

IEC 60601-1-4:1996, *Medical electrical equipment – Part 1: General requirements for safety – 4. Collateral Standard: Programmable electrical medical systems*
Amendment 1[1]

Addition: (to this Particular Standard)

For dated references, subsequent amendments to, or revisions of, the General Standard (IEC 60601-1) or publications referenced in Appendix L, apply to this Particular Standard only when incorporated in it by amendment or revision.

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[1] To be published.

Annex AA
(normative)

Terminology – Index of defined terms

IEC 60601-1: General Standard, clause 2	N.G.2.n.n
IEC 60601-1-n: Collateral Standard, clause 2	C.S-n:2.n.n
IEC 60601-2-n: Particular Standard, clause 2	P.S-n:2.n.n
IEC 60788:	rm-..-..
IEC 60601-2-29: (this publication) clause 2	2.1.10n
Derived term without definition	rm-n-n +
Term without definition	rm-n-n –

Index of terms:	*Source reference:*
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ACCESSORY	N.G.2.1.3
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APPLIED PART	N.G.2.1.5
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ATTENUATION EQUIVALENT	rm-13-37
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ELECTROMAGNETIC COMPATIBILITY (EMC)	C.S-2:2.203.4
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PRIMARY PROTECTIVE SHIELDING rm-64-02
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PROTECTIVE COVER N.G.2.1.17
PROTECTIVE EARTH CONDUCTOR N.G.2.6.7
PROTECTIVE EARTH TERMINAL N.G.2.6.8

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[*] The unamended definition of IEC 60601-1 (1988) applies.

RADIATION rm-11-01
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RADIATION BEAM AXIS rm-37-06
RADIATION DETECTOR rm-51-01
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X-RAY TUBE VOLTAGE rm-36-02

Annex BB
(informative)

Bibliography

ICRP Publication 60:1991, *Recommendations of the International Commission on Radiological Protection*

ICRU Report 39:1985, *Determination of Dose Equivalents Resulting from External Radiation Sources*

ICRU Report 51:1993, *Quantities and Units in Radiation Protection Dosimetry*

(Continued from second cover)

The technical committee responsible for the preparation of this standard has reviewed the provisions of the following International Standards referred in this adopted standard and has decided that they are acceptable for use in conjunction with this standard:

International Standard	*Title*
IEC 60601-1-4 :1996	Medical electrical equipment — Part 1 : General requirements for safety — Section 4 : Collateral standard : Programmable electrical medical systems
IEC 61217 : 1996	Radiotherapy equipment — Coordinates, movements and scales

Only the English language text has been retained while adopting it in this Indian Standard, and as such the page numbers given here are not the same as in the IEC Standard.

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Amendments Issued Since Publication

Amend No.	Date of Issue	Text Affected

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